REMARKS

AMENDMENTS TO THE CLAIMS

Claims 1-52, 61, 63, 64, 67, 68, 86 and 87 have been cancelled. New claim 89 has been added. Claims 53-60, 62, 65-66, 69-85, 88, and 89 are pending.

Claims 53 and 88 have been amended to incorporate the limitation of claims 61 and 63-64. Support for those amendments can be found throughout the specification and in the original claims.

Claim 56 has been amended to recite the term "leucocytes." Support for that amemendment can be found throughout the specification and the original claims, for example at paragraph 103.

UNITY OF INVENTION

The Examiner has maintained the lack of unity holding over Pryjma. In maintaining that holding the Examiner relies upon the assertion that the specification teaches the use of fetal calf serum (FCS) containing cell growth media as a pharmaceutically acceptable carrier. Applicant respectfully disagrees with the Examiner and submits that the teachings of the Pryjma reference do not defeat the unity of the present claims. The passage of the specification seemingly relied on by the Examiner does not state that FCS containing media would be a suitable carrier as presumed by the Examiner. The passage states "The cells should be administered in a pharmaceutically acceptable carrier, which is non-toxic to the cells and the individual. Such carrier may be the growth medium in which the cells were grown, or any suitable buffering medium such as phosphate buffered saline." A skilled artisan would understand that the media can be serum free media or other media that does not contain FCS. For at least that reason, the assertion that Pryjma defeats the unity of invention is incorrect and should be withdrawn. In addition, the Examiner asserts that the references relied upon later in the Office Action also support the lack of unity holding. Applicants respectfully disagree for the reasons set fort in the responses recited below.

In view of the foregoing, Applicant respectfully requests withdrawal of the lack of unity holding and the examination of all pending claims.

OBJECTIONS UNDER 37 C.F.R. § 1.75(C)

Claim 67 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for allegedly failing to further limit the subject matter of t previous claim. Applicant has cancelled claim 67 thereby rendering the objection moot. In view of the foregoing, Applicant respectfully requests withdrawal of the objection.

REJECTIONS UNDER 35 U.S.C § 112, FIRST PARAGRAPH

Claims 53-67 and 73-79 Are Rejected Under 35 U.S.C. 112, First Paragraph As Allegedly Being Non-Enabled

Claims 53-67 and 73-79 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly being non-enabled. The Examiner contends that the specification "does not reasonably provide enablement for: a composition for modulating an immune response in a subject to a target antigen, said composition comprising precursors of antigen-presenting cells, or comprising packed red cells."

Applicant has addressed the Examiner's concerns regarding the use of packed red cells by deleting that element from claim 56 and replacing it with "leucocytes." As such the remainder of Applicant's arguments will be directed to compositions comprising precursors of antigen-presenting cells.

A) The Office Action Fails To Set Forth A Basis Upon Which To Doubt The Objective Truth Of The Statements In The Disclosure.

The Patent Office admits that:

> the specification, [is] enabling for: a composition for modulating an immune response in a subject to a target antigen, said composition comprising antigen-presenting cells, including whole blood, fresh blood, or fractions thereof including peripheral blood mononuclear cells, buffy coat fractions of whole blood, irradiated blood, dendritic cells, monocytes, macrophages, lymphocytes, and neutrophils.

In view of that admission, it is clear that one skilled in the art would know how to make and use the claimed invention with the recited cell types. The Patent Office, however maintains that the "specification does not enable any person skilled in the art to practice the invention without undue experimentation" when the composition comprises precursors of antigen-presenting cells.

MPEP 2164.04 makes clear that "[a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which

correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112 first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein…." (emphasis added).

The analysis set forth in the Office Action neither sets forth a suitable basis upon which to doubt the objective truth of the statements in the disclosure, nor establishes an undue experimental burden exists based upon the alleged unpredictability of the art. In particular, in the original rejection the position taken by the Patent Office was that:

> The specification provides examples that antigen pulsed PBMC can be used to modulate and antigen specific immune response in vivo. PBMC comprise many types of antigen presenting cells including dendritic cells, B cells, and macrophages. However, the specification does not provide any evidence that other types of non-conventional APCs such as NK cells, NKT cells, or red cells, or antigen presenting cell precursors can function to modulate an antigen specific immune response in vivo.

Office Action at page 5. The Patent Office now takes the position that:

> As noted in the original rejection, the highly unpredictable ability of such a precursor cell to function to modulate an immune response in a subject is highly unpredictable. Applicant has not provided any evidence that a non-activated antigen presenting cell precursor population, including non-differentiated hematopoietic stem cells, can function to modulate an immune response in a subject, as claimed.

Office Action at page 5. Applicant respectfully submits that conclusory statements alleging non-enablement merely because something has not been previously shown do not provide a sufficient basis to doubt the objective truth of Applicant's disclosure. Moreover, clear precedent holds that claims "are not invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *See e.g., Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). By asserting that "Applicant has not provided any evidence that non-activated antigen presenting cells… can function to modulate an immune response", the Patent Office seeks to place a burden of proving enablement on Applicant. Office Action at page 6. The PTO bears the burden of making a showing that the specification is not enabled. The PTO cannot place a burden of demonstrating enablement on Applicant without establishing a reason to doubt the enablement of Applicant's claims. The failure of the PTO to meet is legal burden is emphasized by the admission that the claims are enabled for variety of known antigen presenting cells. Office Action at page 3. The PTO's failure to meet its

burden is further emphasized by its concession that the "antigen presenting cell precursors that [are at issue here] can be differentiated into antigen presenting cells were known in the art." Office Action at page 5. Unless and until the PTO can provide more than conclusory statements and allegations of unpredictability as a basis to doubt the objective truth of the statements in the specification, particularly in light of the PTO's admission and concession, the PTO has not met its burden and the rejection should be withdrawn.

B) There Is No Undue Experimentation

The PTO takes the position that there is an undue burden involved in the use of compositions employing precursors of antigen presenting cells. Applicant respectfully disagrees. The "test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction that experimentation is to proceed." *See* MPEP 2164.06 (discussing in its opening paragraph the holding in *In re Wands*, 858, F.2d 731, 737 (Fed. Cir. 1988), additional citations have been omitted). The Examiner proffers no evidence that a skilled artisan might have to undertake anything out of the ordinary in this art when seeking to use the claimed compositions comprising precursors of antigen presenting cells. Furthermore, Applicant submits that the specification describes an assay and that the admittedly enabled cell types can function as positive control(s), both of which indicate that the required experimentation is routine rather than undue.

Claims 86-87 are Rejected Under 35 U.S.C. § 112, First Paragraph as Allegedly Failing to Comply with the Written Description Requirement

Claim 86-87 have been cancelled rendering the rejection moot. In view of the foregoing, Applicant respectfully requests the Examiner to withdraw this rejection.

REJECTIONS UNDER 35 U.S.C § 112 SECOND PARAGRAPH

Claim 87 is rejected under 35 U .S.C. § 112, second paragraph, as allegedly being indefinite for the recitation of "the target antigen." While Applicant respectfully disagrees, in order to advance prosecution claim 87 has been cancelled, thereby rendering the rejection moot.

REJECTIONS UNDER 35 U.S.C § 102

Claims 53-62, 64-67, 73-78,80-83 And 88 Stand Rejected Under 35 U.S.C. § 102(B) As Allegedly Being Anticipated By U.S. Patent 6,080,399

Applicant respectfully disagrees with the rejection over the '399 patent. In order to advance prosecution Applicant has amended independent claims 53 and 88 to incorporate the limitations of claim 63, which was not subject to the rejection over the '399 patent. As nothing the Examiner points to indicates that the '399 patent teaches or fairly suggests the limitations of claim 63, Applicant respectfully submits the rejection should be with drawn.

Claims 53-61, 63, 65-67, 73-75, 76-83, And 86-88 Are Rejected Under 35 U.S.C. § 102(B) As Allegedly Being Anticipated By Venturini Et Al., 2002.

The Examiner has alleged that the methods described in Venturini generate compositions comprising PBMCs as antigen-presenting cells that anticipate the recited claims. Applicant respectfully disagrees.

In order to expedite prosecution Applicant has amended independent claims 53 and 88 to incorporate the limitations of claim 62. As nothing the Examiner points to indicates that Venturini teaches or fairly suggests the limitations of claim 62, Applicant respectfully submits the rejection should be with drawn.

Conclusion

Applicant believes that this response is a complete reply to the Office Action of November 16, 2010. Applicant submits that the each of the foregoing objection and rejections of record should be with drawn in view of the forgoing amendments and responses. It is respectfully submitted that the application is in condition for allowance and a notice of allowance is earnestly requested at the earliest possible time. In the event the Examiner requires any further information, or would like to schedule an interview to advance prosecution in this application, the Examiner is encouraged to contact Applicants' undersigned representatives.

Respectfully submitted,

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/Joseph W. Ricigliano/

Perkins Coie LLP
607 14th St., NW
Suite 800
Washington, DC 20005
Telephone: 202.628 6600
Facsimile: 202.434.1690

Joseph W. Ricigliano (Reg. No. 48,511)
Paul M. Booth (Reg. No. 40,244)
Attorneys for Applicant

Customer No. 91106